

MEDWATCH

FORM FDA 3500A (5/15)

Mfr Report #
UF/Importer Report #
FDA Use Only

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Days(s)	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight NNN.N format <input type="checkbox"/> lb <input type="checkbox"/> kg
In Confidence	or Date of Birth (e.g., 08 Feb 1925) 24 - Mar - 2015		

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander
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B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)	
2. Outcome Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death Include date (dd-mmm-yyyy): 25 - Apr - 2015 <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Congenital Anomaly/Birth Defects <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	
3. Date of Event (dd-mmm-yyyy) 26 - Jun - 2015	4. Date of this Report (dd-mmm-yyyy) 06 - Nov - 2016

5. Describe Event or Problem

Designer note: This is a "layout design" proof of this form. Entry fields and 508-compliance features will be added after this design is approved.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Buttons are not functional on layout design proof.

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7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

(Continue on page 3)

C. SUSPECT PRODUCT(S)

1. Name, Manufacturer/Compounder, Strength	
#1 - Name and Strength	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder	#1 - Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

3. Dose	Frequency	Route Used
#1		
#2		

4. Therapy Dates (If unknown, give duration) from/ to (or best estimate) (dd-mmm-yyyy)	9. Event Abated After Use Stopped or Dose Reduced?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

5. Diagnosis for Use (Indication)	10. Event Reappeared After Reintroduction?
#1 The entry field will allow for two lines of entry text at about this size.	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

6. Is the Product Compounded?	7. Is the Product Over-the-Counter?
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No

8. Expiration Date (dd-mmm-yyyy)
#1 - - - - - #2 - - - - -

D. SUSPECT MEDICAL DEVICE

1. Brand Name	
2. Common Device Name	2b. Procode
3. Manufacturer Name, City and State	
4. Model #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other Removed "Specify" <small>This entry line now has no visual prompt.</small>
Lot#	
Catalog #	Expiration Date (dd-mmm-yyyy)
Serial #	Unique Identifier (UDI) #

6. If Implanted, Give Date (dd-mmm-yyyy)	7. If Explanted, Give Date (dd-mmm-yyyy)
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8. Is this a single-use device that was reprocessed and reused on a patient? Yes No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
 Yes No Returned to Manufacturer on: - - - - -

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address	
Last Name:	First Name:
Address:	
City:	State/Province/Region:
Country:	ZIP/Postal Code:
Phone #:	Email:

2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation (Select from list)	4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. UF/Importer Report Number	
3. User Facility or Importer Name/Address			
4. Contact Person		5. Phone Number	
6. Date User Facility or Importer Became Aware of Event (dd-mmm-yyyy)		7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____	8. Date of This Report (dd-mmm-yyyy)
9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual) Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____		
11. Report Sent to FDA? (If Yes, enter date (dd-mmm-yyyy)) <input type="checkbox"/> Yes _____ <input type="checkbox"/> No _____		12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other: _____ (Specify)	
13. Report Sent to Manufacturer? (If Yes, enter date (dd-mmm-yyyy)) <input type="checkbox"/> Yes _____ <input type="checkbox"/> No _____		14. Manufacturer Name/Address	

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction		2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation	
3. Device Evaluated by Manufacturer? <input type="checkbox"/> Not Returned to Manufacturer <input type="checkbox"/> Yes <input type="checkbox"/> Evaluation Summary Attached <input type="checkbox"/> No (Attach page to explain why not) or provide code: _____		4. Device Manufacture Date (dd-mmm-yyyy) ____ - ____ - ____	
		5. Labeled for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Event Problem and Evaluation Codes (Refer to coding manual) Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____ Method _____ - _____ - _____ - _____ Results _____ - _____ - _____ - _____ Conclusions _____ - _____ - _____ - _____			
7. If Remedial Action Initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Notification <input type="checkbox"/> Repair <input type="checkbox"/> Inspection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Relabeling <input type="checkbox"/> Modification/Adjustment <input type="checkbox"/> Other: _____		8. Usage of Device <input type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown	
		9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number: _____	
10. <input type="checkbox"/> Additional Manufacturer Narrative		and / or 11. <input type="checkbox"/> Corrected Data	

PROOF

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) Name _____ Address _____ Email Address _____ Compounding Outsourcing Facility 503B? <input type="checkbox"/> Yes		2. Phone Number _____	
4. Date Received by Manufacturer (dd-mmm-yyyy) ____ - ____ - ____		3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____	
6. If IND, Give Protocol # _____		5. NDA # _____ ANDA # _____ IND # _____ BLA # _____ PMA/ 510(k) # _____	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____		Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC <input type="checkbox"/> Yes	
9. Manufacturer Report Number		8. Adverse Event Term(s)	

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(CONTINUATION PAGE)

For use by user-facilities,
importers, distributors, and manufacturers
for MANDATORY reporting

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B.5. Describe Event or Problem (continued)

Designer note: The action buttons on pages 2 and 3 temporarily dropped out of the form when the functionally simpler "Acro" PDF file was generated for proof purposes (to allow for combining pages 2 and 3 with the new page 1 PDF that was designed in different software). Those buttons will continue to exist and work in the final "Adobe LiveCycle" functional and 508-compliant PDF form that will be made after FDA approves this revised layout. (In this particular form file you may see residual text from some of the action buttons.)

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B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

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B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

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Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)

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Other Remarks